IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

TONYA EDWARDS, et al.,

Plaintiffs,

v. CIVIL ACTION NO. 2:12-CV-09972

ETHICON, INC., et al.,

Defendants.

MEMORANDUM OPINION & ORDER
(*Daubert* Motions)

Now before the court are several motions filed by the defendants to limit or exclude the testimony of the plaintiffs' proposed experts. For the reasons set forth below, Ethicon's Motion to Exclude the Opinion Testimony of John F. Steege, M.D. [Docket 73] and Ethicon's Motion to Exclude the Opinions and Testimony of Dr. Scott Guelcher, Ph.D. [Docket 97] are **DENIED**. Ethicon's Motion to Limit the Testimony of Bruce Rosenzweig, M.D. [Docket 75] and Motion to Exclude Testimony of Vladimir Iakovlev, M.D. [Docket 85] are **DENIED in part**, **DENIED as moot in part**, and **GRANTED in part**. Ethicon's Motion to Exclude Certain Opinions of Jerry G. Blaivas, M.D. [Docket 77] is **DENIED in part**, **GRANTED in part**, and **RESERVED in part**. Ethicon's Motion to Exclude Ronald Luke, JD, PhD [Docket 79] and Motion to Limit the Testimony of Prof. Dr. Bernd Klosterhalfen are **DENIED in part** and **RESERVED in part**. Ethicon's Motion to Exclude the Opinions and Testimony of Dr. Russell Dunn, Ph.D., P.E. [Docket 91] is **GRANTED in part** and **DENIED in part**. And Ethicon's Motion to Exclude the

Opinions and Testimony of Dr. Abhay Pandit, Ph.D. [Docket 95] is **GRANTED in part** and **DENIED as moot in part**.

I. Background

This case is one of more than 60,000 in seven MDLs that have been assigned to me by the Judicial Panel on Multidistrict Litigation. This case involves surgical mesh products manufactured and sold by the defendants, Ethicon, Inc. and Johnson & Johnson, Inc. (collectively, "Ethicon"), to treat female stress urinary incontinence. The device at issue is Ethicon's Gynecare TVT Obturator ("TVT-O"), which was implanted in the plaintiff, Ms. Edwards. The TVT-O is a medical device that includes a mechanism used to place a mesh tape, or sling, under the urethra to provide support to the urethra. The defendants have filed several motions to exclude or limit the testimony of the plaintiffs' proposed experts pursuant to Federal Rule of Evidence 702 ("Rule 702") and *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993).

II. Standard of Review for *Daubert* Motions

Under Rule 702, expert testimony is admissible if it will "help the trier of fact to understand the evidence or to determine a fact in issue" and (1) is "based upon sufficient facts or data" and (2) is "the product of reliable principles and methods" which (3) has been reliably applied "to the facts of the case." Fed. R. Evid. 702. A two-part test governs the admissibility of expert testimony. The evidence is admitted if it "rests on a reliable foundation and is relevant." *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 597 (1993). The proponent of expert testimony does not have the burden to "prove" anything. He must, however, "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998).

The district court is the gatekeeper.[1] It is an important role: "[E]xpert witnesses have the potential to be both powerful and quite misleading[;]" the court must "ensure that any and all scientific testimony . . . is not only relevant, but reliable." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999) and *Daubert*, 509 U.S. at 588, 595). I "need not determine that the proffered expert testimony is irrefutable or certainly correct"—"[a]s with all other admissible evidence, expert testimony is subject to testing by 'vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (quoting *Daubert*, 509 U.S. at 596); *see also Md. Cas. Co.*, 137 F.3d at 783 (noting that "[a]ll *Daubert* demands is that the trial judge make a 'preliminary assessment' of whether the proffered testimony is both reliable . . . and helpful").

Daubert mentions specific factors to guide the overall relevance and reliability determinations that apply to all expert evidence. They include (1) whether the particular scientific theory "can be (and has been) tested"; (2) whether the theory "has been subjected to peer review and publication"; (3) the "known or potential rate of error"; (4) the "existence and maintenance of standards controlling the technique's operation"; and (5) whether the technique has achieved "general acceptance" in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593-94).

Despite these factors, "[t]he inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions

[1] With more than 60,000 cases related to surgical mesh products currently pending before me, this gatekeeper role takes on extraordinary significance. Each of my evidentiary determinations carries substantial weight with the remaining surgical mesh cases. Regardless, while I am cognizant of the subsequent implications of my rulings in these cases, I am limited to the record immediately before me and the arguments of counsel.

reached." *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594-95); *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999) ("We agree with the Solicitor General that '[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony.'") (citation omitted); *see also Crisp*, 324 F.3d at 266 (noting "that testing of reliability should be flexible and that *Daubert*'s five factors neither necessarily nor exclusively apply to every expert").

With respect to relevancy, *Daubert* also explains:

> Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of fit. Fit is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. . . . Rule 702's helpfulness standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

Daubert, 509 U.S. at 591-92 (internal citations and quotation marks omitted).

Finally, in several of the instant *Daubert* motions, a specific scientific methodology comes into play, dealing with differential diagnoses or etiologies. "Differential diagnosis, or differential etiology, is a standard scientific technique of identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated." *Westberry*, 178 F.3d at 262. The Fourth Circuit has stated that:

> A reliable differential diagnosis typically, though not invariably, is performed after "physical examinations, the taking of medical histories, and the review of clinical tests, including laboratory tests," and generally is accomplished by determining the possible causes for the patient's symptoms and then eliminating each of these potential causes until reaching one that cannot be ruled out or determining which of those that cannot be excluded is the most likely.

Id. A reliable differential diagnosis passes scrutiny under *Daubert*. An unreliable differential diagnosis is another matter:

> A differential diagnosis that fails to take serious account of other potential causes may be so lacking that it cannot provide a reliable basis for an opinion on causation. However, "[a] medical expert's causation conclusion should not be excluded because he or she has failed to rule out every possible alternative cause of a plaintiff's illness." The alternative causes suggested by a defendant "affect the weight that the jury should give the expert's testimony and not the admissibility of that testimony," unless the expert can offer "no explanation for why she has concluded [an alternative cause offered by the opposing party] was not the sole cause."

Id. at 265-66 (internal citations omitted).

III. Discussion

Ethicon has moved to limit or exclude the testimony of several of the plaintiffs' proposed experts. Each motion is addressed below.

Before I begin, I will address two arguments that apply to many of Ethicon's *Daubert* motions. First, as I have repeated throughout these MDLs, I will not permit the parties to use experts to usurp the jury's fact-finding function to determine Ethicon's state of mind, or whether Ethicon acted reasonably. *See, e.g., In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611, 629 (S.D. W. Va. 2013); *In re Ethicon, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, 2:12-MD-02327, 2014 WL 186872, at *6, 21 (S.D. W. Va. Jan. 15, 2014). While an expert may testify as to a review of internal corporate documents solely for the purpose of explaining the basis for his or her opinions—assuming the opinions are otherwise admissible—Ethicon's knowledge, state of mind, or other matters related to corporate conduct and ethics are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury. Similarly, "opinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible." *United States v. McIver*, 470 F.3d 550, 562 (4th Cir. 2006). I will not repeatedly parse the expert reports and depositions of each expert in relation to this same objection. I trust that

able counsel in this matter will tailor expert testimony at trial accordingly.

Second, Ethicon repeatedly argues that expert opinions relating to polypropylene do not apply to the Prolene mesh used in the TVT-O. Ethicon states that experts testifying about polypropylene fail "to account for the important chemical differences between generic polypropylene and PROLENE, which is an isotactic form of polypropylene that has been treated with two proprietary antioxidants." (*See* Defs.' Mem. of Law in Supp. of Mot. to Exclude the Test. and Ops. of Dr. Scott Guelcher, Ph.D. [Docket 98], at 4). This appears to be an argument wholly conceived by lawyers, unfounded in science. The experts in this case, including Ethicon's experts, testify as to "polypropylene" and its propensities. This is a strong indication that Ethicon's argument is disingenuous. It is clear that the experts in this case do not consider Prolene to be different from polypropylene for the purposes of their opinions in this case. Therefore, to the extent that Ethicon contends that an expert's opinions are unreliable or unhelpful because they do not account for the "important chemical differences" between polypropylene and Prolene, this argument is rejected.

Third, Ethicon argues repeatedly that several of the plaintiffs' experts should be excluded because the testing Dr. Iakovlev performed on Ms. Edwards's explant allegedly rendered the explant untestable. As more fully set forth in Section III.F., *infra*, Dr. Iakovlev's opinions regarding Ms. Edwards's mesh pass muster under Federal Rule of Evidence 702. Therefore, any arguments that other experts' testimony should be excluded because Dr. Iakovlev's testimony is inadmissible are denied.

A. Motion to Exclude Opinion Testimony of John F. Steege, M.D.

Dr. Steege is an obstetrician and gynecologist. He teaches and studies the etiology or

"causes" of chronic pelvic pain, vaginal pain, and sexual pain. (*See* Steege Report [Docket 73-6], at 1). In his expert report, Dr. Steege discusses the etiology of problems associated with using mesh in gynecologic surgery. (*See id.* at 2-11). In addition, Dr. Steege opines that the TVT-O IFU failed to reflect potential mesh-related complications. (*See id.* at 11-12). Finally, Dr. Steege provides an assessment of Ms. Edwards's current medical condition. (*See id.* at 18-23).

Ethicon moves to exclude Dr. Steege's opinions entirely. Ethicon argues that Dr. Steege's specific causation opinions are unreliable because Dr. Steege did not conduct a proper differential diagnosis to rule out alternative causes of Ms. Edwards's chronic pelvic pain. Ethicon also contends that Dr. Steege's general opinions regarding mesh complications exceed the scope of his qualifications. In addition, Ethicon argues that certain of Dr. Steege's general opinions regarding mesh are unreliable because they are based upon the unreliable methodology of other designated experts. Finally, Ethicon argues that Dr. Steege's general opinions are irrelevant to the plaintiffs' claims and should be excluded because they are cumulative. For the reasons discussed below, Ethicon's motion [Docket 73] is **DENIED**.

1. General Causation Opinions

In his report, Dr. Steege provides several opinions regarding alleged problems associated with surgically implanted mesh, including: "[c]hronic inflammation of native tissue surrounding the mesh"; "[s]hrinkage and deformation of mesh"; "[d]irect trauma to nerves, incurred during the mesh implantation or explanation process"; "[n]erve irritation, distortion, and entrapment in the mesh and the surrounding fibrosis"; "[m]esh-related neuropathy"; and "[a]lteration of the function of surrounding organs due to any or all of" the above-described mechanisms. (Steege Report [Docket 73-6], at 2).

Ethicon contends that Dr. Steege is unqualified to offer these general causation opinions because he has never performed a TVT, TVT-O, or mesh-related procedure to treat SUI (*see* Steege Dep. [Docket 73-5], at 113:14-114:2); has not taught any courses or conducted any studies regarding the TVT-O procedure. (*see id.* at 136:17-137:16); and has not handled explanted mesh, examined the biomechanical properties of mesh, or performed degradation testing of mesh (*see id.* at 156:16-19, 242:17-21).

After reviewing Dr. Steege's report and curriculum vitae, I **FIND** that Dr. Steege is qualified to opine on the etiology of problems associated with the implantation of mesh products in gynecologic surgery. An expert may be qualified by "knowledge, skill, experience, training, or education[.]" Fed. R. Evid. 702. "One knowledgeable about a particular subject need not be precisely informed about all details of the issues raised in order to offer an [expert] opinion." *Thomas J. Kline, Inc. v. Lorillard, Inc.*, 878 F.2d 791, 799 (4th Cir. 1989). Dr. Steege is a renowned teacher and physician who specializes in the etiology of chronic pelvic pain, vaginal pain, and sexual pain. He is the Director of the Division of Laparoscopy and Pelvic Pain at the University of North Carolina at Chapel Hill and a professor of obstetrics and gynecology. (*See* Steege Report [Docket 73-6], at 1). In addition, Dr. Steege has treated 15-20 patients who complained of pain after being implanted with a mesh product. (*See* Steege Dep. [Docket 73-5], at 153-56).

Ethicon also argues that Dr. Steege's general causation opinions do not fit the facts of this case and are therefore unhelpful. Ethicon contends that because Dr. Steege has not examined Ms. Edwards's explanted mesh, he cannot connect his general causation opinions to Ms. Edwards's injuries. Therefore, Ethicon concludes that Dr. Steege's general causation opinions are irrelevant

to the plaintiffs' claims. Ethicon is incorrect that Dr. Steege's *general causation* testimony—that the TVT-O mesh can degrade, fray, or lose particles—should be excluded under Rule 702 simply because the plaintiffs' may fail to carry their burden as to *specific causation*—that Ms. Edwards was injured by the TVT-O mesh. If Ethicon believes the plaintiffs ultimately fail to carry their burden, it is free to make that argument at trial.

Based upon the foregoing, I **FIND** that Dr. Steege is qualified to testify regarding mesh degradation.

2. Specific Causation Opinions

Dr. Steege provides a case-specific assessment of Ms. Edwards. After reviewing Ms. Edwards's medical history and conducting a physical, abdominal, and gynecological examination, Dr. Steege concludes that Ms. Edwards's "persistent sexual discomfort, pelvic pain, and groin pain are the result of a neuropathy from the transobturator sling procedure and mesh excision, most likely from an obturator nerve injury." (Steege Report [Docket 73-6], at 22). He also concluded "to a reasonable degree of medical certainty" that "Ms. Edwards had scarring and inflammation from synthetic mesh placed through the obturator." (*Id.*). Finally, Dr. Steege concluded that Ms. Edwards's "pelvic pain, and sexual symptoms are secondary to the placement and subsequent excision of the sling and, more likely than not, obturator neuropathy." (*Id.* at 23). These conclusions were based on Dr. Steege's "knowledge of pelvic neuroanatomy, the inflammatory response of tissue to foreign bodies, and [his] professional opinion." (*Id.*). Ethicon claims that Dr. Steege's specific causation opinion is unreliable because Dr. Steege did not properly conduct a differential diagnosis. For the reasons that follow, I reject Ethicon's arguments.

Ethicon claims that Dr. Steege did not properly conduct a differential diagnosis of Ms. Edwards because he did not consider other factors that could have caused her injury. Specifically, Ethicon claims that Dr. Steege did not attempt to rule out other potential sources of Ms. Edwards's chronic pain and did not conduct a sufficient examination to rule out endometriosis as an alternative cause.

In his report, Dr. Steege acknowledges several alternative causes of Ms. Edwards's pain. Specifically, Dr. Steege's report notes that Ms. Edwards had three vaginal deliveries, underwent several surgeries, and suffers from chronic neck pain. (*See* Steege Report [Docket 73-6], at 18-23). Dr. Steege has testified that he "very carefully" examined Ms. Edwards's medical records before coming to his conclusion. (Steege Dep. [Docket 108-2], at 299:3-5). He also testified that, based on his clinical experience, it would be very rare for orthopedic conditions to cause pelvic spasms and pain. (*Id.* at 30:1-31:2). Dr. Steege concluded:

> I believe [Ms. Edwards's] groin pain, pelvic pain, and sexual symptoms are secondary to the placement and subsequent excision of the sling and, more likely than not, obturator neuropathy. These conclusions are based off of my knowledge of pelvic neuroanatomy, the inflammatory response of tissue to foreign bodies, and my professional opinion. These opinions are supported by well-established scientific principles accepted by the medical community and published in the scientific literature. In reaching these conclusions, I considered and ruled out other causes of chronic neuropathic pain.

(Steege Report [Docket 73-6], at 23).

While Dr. Steege did not provide a detailed explanation as to why he ruled out these alternative causes, he bases his conclusions on accepted scientific principles and research. In addition, he reviewed Ms. Edwards's medical history and conducted a diagnostic examination to determine the cause of Ms. Edwards's pain. (*See* Steege Report [Docket 73-6], at 18-23). Although he did not clearly connect these scientific studies and examinations to his opinion, it cannot be said

that he provided *no explanation* as to why he ruled out alternative causes. *See, e.g.*, *Heller v. Shaw Indus.*, 167 F.3d 146, 156 (3d Cir. 1999) ("Dr. Papano did not offer detailed explanations for why he concluded that these were not the causes of plaintiff's illness, but his responses [during cross-examination], grounded in the alleged temporal relationship, the results of Todd's testing showing a reduction in VOCs when the carpet was removed, and Heller's medical history and physical examination, certainly are more than '*no* explanation.'"). Accordingly, I **FIND** that Dr. Steege used a sufficiently reliable methodology to ascertain the cause of Ms. Edwards's chronic pelvic pain.

Ethicon also argues that Dr. Steege failed to conduct a sufficient examination to exclude endometriosis as a source of Ms. Edwards's chronic pelvic pain. In his deposition, Dr. Steege testified that "I would [] comment that neither patient we're dealing with [including Ms. Edwards] had endometriosis for the record." (Steege Dep. [Docket 73-5], at 161:20-21). Dr. Steege testified that endometriosis is a common health problem for women. (*See id.* at 161:10-19). Dr. Steege testified that endometriosis can be diagnosed with a physical examination, but that the condition is often diagnosed by reviewing the patient's history and conducting a diagnostic laparoscopy:

> Q. How do you determine whether or not a patient has endometriosis?
>
> A. By taking a history and physical exam in detail and those where it's clinically relevant a high index of suspicion and do a laparoscopy. Typically the person who comes to see me, though, has already had the diagnosis made because they've had four laparoscopies, some of which they didn't need. So I don't need another one.

(Steege Dep. [Docket 108-2], at 170:11-24).

Dr. Steege further testified that "I would say that the decision to do a laparoscopy is based on the totality of the history and physical exam to see if there's enough evidence to support the

possibility. You certainly do not laparoscope every patient with pelvic pain." (*Id.* at 164:1-5). In addition, during his deposition, Dr. Steege referred to a study indicating that physicians relying on a patient's history and physical examination correctly diagnosed endometriosis eighty percent of the time. (*See id.* at 164-65:9-21). In Ms. Edwards's case, although he conducted a physical examination of Ms. Edwards, he did not conduct a diagnostic laparoscopy to determine whether she had endometriosis. (*See* Steege Report [Docket 73-6], at 21).

"[A] physician need not conduct every possible test to rule out all possible causes of a patient's illness, 'so long as he or she employed sufficient diagnostic techniques to have good grounds for his or her conclusion.'" *Heller*, 167 F.3d at 156 (quoting *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 761 (3d Cir. 1994)). Here, although Dr. Steege did not conduct a laparoscopy, he did conduct a physical examination and review Ms. Edwards's history, which Dr. Steege demonstrated is a reliable means of diagnosing endometriosis. Accordingly, I **FIND** that Dr. Steege used a sufficiently reliable methodology to exclude endometriosis as a possible source of Ms. Edwards's chronic pelvic pain.

3. Opinions Relying on Dr. Iakovlev's Testimony

Ethicon also argues that certain of Dr. Steege's opinions should be excluded because they are based upon Dr. Iakovlev's testimony, which Ethicon contends is unreliable. As fully set forth below, Dr. Iakovlev's testimony regarding Ms. Edwards's explant survives Ethicon's challenge. Additionally, Ethicon's argument that Dr. Steege based his opinions on Dr. Iakovlev's findings is simply incorrect. Dr. Steege testified that he reviewed Dr. Iakovlev's report and photographs of Ms. Edwards's mesh. (*See* Steege Dep. [Docket 108-2], at 117-18). However, Dr. Steege explicitly stated that his opinions "were not dependent upon" the materials sent to him by Dr. Iakovlev. (*Id.*

at 119). Rather, the materials provided by Dr. Iakovlev "reinforced" Dr. Steege's opinions and "supported [his] opinions strongly." (*Id.* at 119:22-24, 120: 11-17). I therefore **FIND** that Ethicon's motion on this issue is without merit.

4. Cumulative Nature of Dr. Steege's Opinions

Finally, Ethicon argues that certain of Dr. Steege's opinions should be excluded because they overlap with the opinions of Dr. Rosenzweig, another of the plaintiffs' experts. Ethicon argues that "[a]llowing each of these . . . designated experts to opine on the same general, non-plaintiff-specific subject matters would constitute a needless presentation of cumulative evidence." (Mem. in Supp. of Defs.' Mot. to Exclude the Op. Test. of John F. Steege, M.D. [Docket 74], at 14). Some of Dr. Steege's and Dr. Rosenzweig's opinions are similar in nature. To that end, the parties have been warned that repetitive expert testimony will not be allowed. However, without knowing the order in which the plaintiffs' experts will testify or precisely to what each expert will testify, I cannot deny Dr. Steege's testimony on this basis alone. Therefore, Ethicon's motion on this point is **DENIED**.

B. Motion to Limit the Testimony of Bruce Rosenzweig, M.D.

Dr. Rosenzweig is a urogynecologist and professor of obstetrics and gynecology. He offers several different opinions, each of which Ethicon contends is improper: (1) opinions regarding the sufficiency of warnings set out in the TVT-O Instructions for Use ("IFU") and other promotional materials; (2) opinions that Ethicon failed to provide adequate training; (3) opinions that the TVT-O causes an increased risk of infection; (4) opinions that the TVT-O degrades in vivo and is subject to fraying and particle loss; and (5) opinions regarding mesh shrinkage or contracture. For

the reasons discussed below, Ethicon's motion [Docket 75] is **GRANTED in part**, **DENIED in part**, and **DENIED as moot in part**.

1. Opinions Related to Sufficiency of Warnings on the IFU and Promotional Materials

Dr. Rosenzweig opines that the TVT-O's IFU was inadequate, that Ethicon failed to inform patients and physicians about particular risks of the TVT-O, and that the TVT-O's marketing materials were inaccurate or incomplete. (*See* Rosenzweig Report [Docket 75-1], at 3). Ethicon first argues generally that Dr. Rosenzweig is not qualified to testify about product warnings because he has not drafted an IFU. While it is true that Dr. Rosenzweig has not personally drafted an IFU, Dr. Rosenzweig's testimony reveals that he has consulted on product warnings in the past:

Q. Have you ever prepared IFUs?

A. Well, I did work with Gish Biomedical to get the information that they needed to put in the amnioinfusion catheter IFU.

Q. Did you actually draft the IFU?

A. No, I did not. I worked as a consultant on that.

Q. Have you ever drafted an IFU?

A. No, I have not.

Q. Have you ever drafted a patient brochure?

A. I worked on the amnioinfusion catheter brochures, yes.

(Rosenzweig Dep. [Docket 75-3], at 53:17-54:4). Dr. Rosenzweig also testified that he served on another company's scientific advisory committee that worked on similar documents. (*See id.* at 54:10-12). In his expert report, Dr. Rosenzweig states that he has reviewed "numerous" IFUs for a "variety of products including mesh products in order to understand the proper way to use the

device and to gain knowledge about the complications and adverse events associated with the device." (Rosenzweig Report [Docket 75-1], at 55). Further, as a urogynecologist, Dr. Rosenzweig is qualified to opine about the risks of the TVT-O and pelvic mesh surgery and whether those risks were adequately expressed on the TVT-O's IFU. I therefore **FIND** that Dr. Rosenzweig is qualified to testify generally on the adequacy of the TVT-O's product warnings and marketing materials.[2]

Finding Dr. Rosenzweig qualified to opine generally about the TVT-O's warnings and marketing materials, I now turn to Ethicon's specific objections in relation to particular product warning opinions.

2. Cancer

The plaintiffs state that Dr. Rosenzweig will not testify about cancer. (*See* Pls.' Resp. to Defs.' Mot. to Limit the Test. of Bruce Rosenzweig, M.D. [Docket 106], at 7). Accordingly, Ethicon's motion on this subject is **DENIED as moot**.

3. Cytotoxicity

Dr. Rosenzweig states in his expert report that an internal Ethicon document suggested that polypropylene mesh was cytotoxic. (*See* Rosenzweig Report [Docket 75-1], at 105). Cytotoxicity refers to a material's potential to cause cell death. Dr. Rosenzweig writes that Ethicon failed to undertake testing "to determine whether the marked cytotoxicity found in the TVT mesh had long term consequences for permanent human use." (*Id.* at 105-06). He then opines that Ethicon failed to act as a "reasonably prudent medical device manufacturer" because it "failed to inform

[2] Ethicon argues that my decision in the C. R. Bard MDL to preclude Dr. Bob Shull from testifying about product warnings should control here. *See In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 611 (S.D. W. Va. 2013). But there, Dr. Shull *admitted* that he had not developed product warnings, had no experience in that area, and did not hold himself out as an expert in product warnings. *See id.* Dr. Rosenzweig has made no similar admissions. Therefore, my holdings regarding Dr. Shull are inapposite.

physicians and their patients about the risk of its mesh being cytotoxic[].” (*Id.* at 106).

According to Ethicon, cytotoxicity testing “does not represent *in vivo* testing, and toxicological experience is required to extrapolate the results to humans.” (Mem. in Supp. of Mot. to Limit the Test. of Bruce Rosenzweig, M.D. [Docket 76], at 6). Ethicon therefore argues that this testimony exceeds Dr. Rosenzweig’s qualifications because he does not have toxicological experience, and he admits that he has never conducted toxicity or cytotoxicity testing of mesh. (*See* Rosenzweig Dep. [Docket 75-3], at 222:4-6). Ethicon also argues that this testimony is unreliable because the internal Ethicon study cited by Dr. Rosenzweig states that “this clinical data provides important evidence that the cytotoxicity of the [polypropylene] mesh observed in vitro does not translate into any clinical significance or adverse patient outcomes.” (Cytotoxicity Risk Assessment for the TVT (Ulmsten) Device [Docket 75-7]).

I **FIND** that Dr. Rosenzweig is qualified to offer the opinion that Ethicon failed to inform physicians about the risk that the TVT-O is cytotoxic. Although Dr. Rosenzweig is not a toxicologist, he stated that he regularly encounters cytotoxicity in his practice, including in women who have polypropylene mesh implants. (*See* Rosenzweig Aff. [Docket 106-6] ¶ 4). He also stated that he has “removed mesh implants, including the TVT, as a result of cytotoxicity.” (*Id.* at ¶ 4).

I also **FIND** that this opinion is sufficiently reliable. Dr. Rosenzweig relies on an internal Ethicon finding that the mesh used in the TVT-O was cytotoxic. Further, Dr. Rosenzweig states that the potential for cytotoxicity is important information that physicians need to know. (*See* Rosenzweig Report [Docket 75-1], at 106). To the extent that Ethicon believes cytotoxicity is not clinically significant, it may cross examine Dr. Rosenzweig on that issue. Therefore, Ethicon’s motion with respect to Dr. Rosenzweig’s opinions about the failure to warm about cytotoxicity is

DENIED.

However, I **FIND** that Dr. Rosenzweig is not qualified to opine that Ethicon's testing was insufficient. There is no indication that Dr. Rosenzweig has any experience or knowledge on the appropriate testing a medical device manufacturer should undertake. Therefore, Dr. Rosenzweig's testimony that Ethicon failed to appropriately test for cytotoxicity is **EXCLUDED**.

4. TVT-O Appropriateness for Certain Populations

Dr. Rosenzweig will also testify that "Ethicon promoted the TVT-O as a 'reproducible' technique that was appropriate for all patients," when in fact it was less efficacious for certain types of women, including obese women, older women, active women, diabetics, smokers, Asian women, and African-American women. (Rosenzweig Report [Docket 75-1], at 77-80). He claims that Ethicon should have warned physicians of risks to these different populations. In support, he simply reviews deposition testimony and internal documents of Ethicon employees expressing concerns about the TVT-O's adaptability to different populations. For instance, Dr. Rosenzweig quotes deposition testimony of Ethicon's Medical Director to show that "obese patients do not fare well with these devices." (*Id.* at 77). He also reviews a document wherein the inventor of the TVT-O stated that the TVT-O was inappropriate for treatment in younger, active women. (*See id.* at 78).

As the plaintiffs concede, much of this opinion is not relevant to Ms. Edwards's case and should be excluded. (*See* Pls.' Resp. to Defs.' Mot. to Limit the Test. of Bruce Rosenzweig, M.D. [Docket 106], at 8-9). The only portions of this opinion that are relevant are the TVT-O's appropriateness for younger, active women, and the TVT-O's appropriateness for obese women, categories into which Ms. Edwards falls. But it is not helpful to the jury to have Dr. Rosenzweig

read a document explaining what the inventor of the TVT-O thought about this. The jury is capable of reading that document itself. *See In re Prempro Prods. Liab. Litig.*, 554 F. Supp. 2d 871, 887 (E.D. Ark. 2008); Fed. R. Evid. 702 ("the expert's scientific, technical, or other specialized knowledge" must "help the trier of fact to understand the evidence"). Therefore, Dr. Rosenzweig's opinion that Ethicon should have warned that the TVT-O could be more dangerous for certain populations is **EXCLUDED**.

5. Adverse Event Reporting

Dr. Rosenzweig opines that "Ethicon's collection and reporting of adverse events and complications to physicians and patients was incomplete, inaccurate, and misleading." (Rosenzweig Report [Docket 75-1], at 98). Ethicon argues that Dr. Rosenzweig is unqualified to offer this opinion and it is unreliable. The plaintiffs concede that Dr. Rosenzweig will not offer this opinion at trial. (Pls.' Resp. [Docket 106], at 10). Therefore, this aspect of Ethicon's motion is **DENIED as moot**.

6. Failure to Provide Adequate Training

Dr. Rosenzweig opines that Ethicon "failed to provide adequate training" to physicians regarding the use of the TVT-O. (Rosenzweig Report [Docket 75-1], at 3). However, instead of commenting on the quality of training, Dr. Rosenzweig reviews corporate documents showing that Ethicon cut funding for professional trainings which Dr. Rosenzweig says "contrasted" with Ethicon's corporate credo. (*See id.* at 74-77). Not only is this opinion simply a narrative review of corporate documents, which is not helpful to the jury, but it is unreliable because Dr. Rosenzweig fails to describe the basis for his opinion that Ethicon's training was inadequate. Therefore, this portion of Dr. Rosenzweig's opinion is **EXCLUDED**.

7. Infections

Dr. Rosenzweig opines that the TVT-O mesh and implantation procedure carry an increased risk of infection. (*See id.* at 26). Ethicon does not challenge the reliability of this opinion; rather, it argues that this opinion is not helpful to the jury because Ms. Edwards has not suffered from a mesh-related infection. However, Ms. Edwards's medical records indicate that she has suffered from infections. For example, the progress notes from an examination of Ms. Edwards the month after her implant state that she suffered from a primary infection after her surgery. (*See* Kaiser Permanente Progress Notes [Docket 106-15], at 2). Additionally, a pathology report on Ms. Edwards indicated that she was suffering from "soft tissue with chronic inflammation and focal foreign body giant cell reaction" (Emory Healthcare Pathology Report [Docket 106-16]) and Dr. Rosenzweig stated in his deposition that chronic inflammation can be a sign of infection (*see* Rosenzweig Dep. [Docket 106-12], at 25:10-22). Therefore, contrary to Ethicon's arguments, infections are a fact in issue in this case, and Ethicon's motion, as presented on this issue, is **DENIED**.

8. Degradation and Fraying

Dr. Rosenzweig will testify that the TVT-O is defective because its mesh degrades in vivo and is subject to fraying and particle loss. (*See* Rosenzweig Report [Docket 75-1], 11-20, 34-46). Ethicon first argues that Dr. Rosenzweig is unqualified to offer these opinions because he does not have a background in polymer chemistry, has never studied biomaterials, and has never done any bench or lab research regarding polypropylene. I disagree. As I stated in relation to *Lewis v. Johnson & Johnson*,

> Simply because Dr. Rosenzweig has not personally performed pathology research on polypropylene explants does not necessarily render him unqualified under Rule

> 702 to offer opinions regarding the suitability of the TVT device for implantation. An expert may be qualified by "knowledge, skill, experience, training, or education." Fed. R. Evid. 702. "One knowledgeable about a particular subject need not be precisely informed about all details of the issues raised in order to offer an [expert] opinion." *Thomas J. Kline, Inc. v. Lorillard, Inc.*, 878 F.2d 791, 799 (4th Cir. 1989).
>
> Dr. Rosenzweig has performed over a thousand pelvic floor surgical procedures, and over 200 surgeries dealing with complications related to synthetic mesh, including the removal of numerous TVT devices. Dr. Rosenzweig testified that as early as 2004 or 2005, he determined, as a result of explanting mesh products, that polypropylene degrades in the human body. Further, he cites dozens of studies and academic papers in his expert report to support his opinion that vaginally implanted polypropylene mesh degrades. I therefore **FIND** that Dr. Rosenzweig is qualified to offer the opinion that the TVT is not suitable for permanent implantation to treat stress urinary incontinence.

In re Ethicon, Inc., Pelvic Repair Sys. Prods. Liab. Litig., 2:12-MD-02327, 2014 WL 186872, at *20 (S.D. W. Va. Jan. 15, 2014) (internal citations and quotation marks omitted). I **ADOPT** that holding here.

With respect to Dr. Rosenzweig's general causation opinions that the mesh used in the TVT-O degrades, frays, and loses particles, Ethicon contends that these opinions are not helpful to the jury. According to Ethicon, "neither Dr. Rosenzweig nor any of Plaintiffs' other experts can reliably testify (1) that the mesh in Ms. Edwards'[s] TVT-O device *actually* degraded, frayed, or lost particles, or (2) that any such degradation, fraying, or particle loss proximately caused Ms. Edwards'[s] injuries." (Mem. in Supp. of Mot. to Limit the Test. of Bruce Rosenzweig, M.D. [Docket 76], at 12). As with Dr. Steege's testimony, discussed above, Ethicon is incorrect that Dr. Rosenzweig's *general causation* testimony—that the TVT-O mesh can degrade, fray, or lose particles—should be excluded under Rule 702 simply because the plaintiffs' might fail to carry their burden as to *specific causation*—that Ms. Edwards was injured by the TVT-O mesh. If Ethicon believes the plaintiffs ultimately fail to carry their burden, it is free to make that argument

at trial.

Based upon the foregoing, I **FIND** that Dr. Rosenzweig may testify regarding mesh degradation.

C. Motion to Exclude Certain Opinions of Jerry G. Blaivas, M.D.

Dr. Blaivas is a urologist and one of the pioneers of sling surgery for women with sphincter incontinence. (*See* Blaivas Report [Docket 77-1], at 1). He has extensive experience treating patients with complications related to synthetic sling surgery. (*See id.* at 2-3). Ethicon seeks to exclude parts of Dr. Blaivas's testimony because they exceed his qualifications, are unhelpful to the jury, or are not set out in his expert report. For the reasons discussed above, Ethicon's motion [Docket 77] is **GRANTED in part**, **DENIED in part**, and **RESERVED in part**.

1. Opinions Related to Product Warnings

Dr. Blaivas opines that Ethicon failed to warn physicians about particular complications with the TVT-O. For example, Dr. Blaivas states in his report that:

> 6. *Ethicon should have warned physicians and patients about the possibility of serious and life-style altering complications* (e.g. 9, 21-33). Ethicon knew or should have known about the potential for serious complications from mesh slings, such as the Gynecare TVT-O, *because of the known experience with Mersilene, Marlex and silastic slings that were performed during the last three decades of the 20th century, and more recently the Protegen and Mentor ObTape slings.*
>
> . . .
>
> 11. *Ethicon did not warn doctors and patients about the chronic and lifestyle altering nature of the complications associated with its products . . .*
>
> 12. *Ethicon did not warn doctors and patients about the difficulty removing their products . . .* and the poor or less than optimal results when excision or revision becomes warranted due to complications.

. . .

16. From a scientific and ethical perspective, *Ethicon should have had a high index of suspicion relating to the product defects based on previous experience with predicate products*. . . . *Since many of these complications occurred many months or years after the original surgery, Ethicon should have taken appropriate measures to investigate this and also warn physicians and patients about the possibility of these late-onset complications.* At the very least there should have been a simple statement about the possibility that such complications could arise in the future after months, years, or even decades and that the technique is new, so long term studies are not yet available to determine the ultimate safety and efficacy. The many serious complications that I have seen and that occurred with the two plaintiffs discussed in this report do not appear in any study.

. . .

25. The TVT-O IFUs state that "animal studies show that implantation of PROLENE mesh elicits a minimal inflammatory reaction in tissues, which is transient and is followed by the deposition of a thin layer of tissue, that can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes." *Despite literature to the contrary, Ethicon never changed the IFU to reflect: 1) the inflammatory response is persistent and not transient; 2) the mesh creates dense scar tissue not a 'thin layer of tissue'; and 3) the material is, in fact, subject to degradation*[.]

. . .

32. I have reviewed the Material Safety Data Sheet for the polypropylene used in the Gynecare TVT-O medical device. . . . Ethicon IFUs do not include the toxic and carcinogenic warnings contained in the MSDSs. Ethicon marketing materials for doctors and patients do not include the toxic and carcinogenic warnings contained in the MSDSs.

. . .

Ethicon did not adequately warn doctors and patients about the kind of complications experienced by Mrs. Edwards . . . .

(Blaivas Report [Docket 77-1], at 7-16 (emphasis added)).[3]

Ethicon first challenges Dr. Blaivas's qualifications to give these opinions because Ethicon argues that Dr. Blaivas is not an expert on product warnings. But Dr. Blaivas need not be an expert on product warnings per se. Rather, as a urologist, Dr. Blaivas is qualified to testify about the risks of implanting the TVT-O and whether those risks were adequately expressed on the TVT-O's IFU. Dr. Blaivas is qualified to render an opinion as to the completeness and accuracy of Ethicon's warning and—"it follows from that—the extent to which any inaccuracies or omissions could either deprive a reader or mislead a reader of what the risks and benefits" of the TVT-O was when the warnings were published. *In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prods. Liab. Litig.*, MDL 1203, 2000 WL 876900, at *11 (E.D. Pa. June 20, 2000). I therefore **FIND** that Dr. Blaivas is qualified to render opinions about the adequacy of the TVT-O's IFU.

Ethicon contends that any opinions about its alleged failure to warn about infections are irrelevant because there is no evidence that Ms. Edwards suffered from a mesh-related infection. However, as discussed in Section III.B.7, *supra*, there is evidence that Ms. Edwards suffered from infection following her implant. Therefore, contrary to Ethicon's arguments, infections are a fact in issue in this case.

2. Opinions Relating to Complications

Ethicon argues that several of Dr. Blaivas's opinions concerning mesh-related complications should be excluded because they are unreliable or irrelevant

a. Alleged Under-Reporting of Mesh Complications

[3] Ethicon argues that some of this testimony is inadmissible evidence of Ethicon's corporate knowledge or state of mind. As I previously stated, I will not parse expert reports in relation to this objection. However, the parties are cautioned that experts must offer opinions that utilize their "scientific technical, or other specialized knowledge[.]" Fed. R. Evid. 702.

Dr. Blaivas opines that "[m]esh complications are significantly under-reported." (Blaivas Report [Docket 77-1], at 7). Ethicon argues that this opinion is unreliable because it is based on Dr. Blaivas's personal conversations with other physicians, but Dr. Blaivas could not identify which particular doctors had discussed this issue with him. (*See* Blaivas Dep. [Docket 77-2], at 108-09).

Dr. Blaivas did not rely *solely* on personal conversations with other physicians. He also relied on peer-reviewed studies, including two studies that compared independent reports of complications to the complications reported in the peer-reviewed literature. (*See* Blaivas Report [Docket 77-1], at 7). In the first study, the authors compared mesh-related complications reported in the scientific literature to complications reported to the Manufacturer and User Facility Device Experience ("MAUDE") database. (*See* Donna Y. Deng et al., *Presentation and Management of Major Complications of Midurethral Slings: Are Complications Under-Reported?* 52 J. Urology 46, 46 (2007) [Docket 77-7]). In particular, the authors reviewed twenty-eight scientific studies involving the TVT, SPARC, Uratape, Monarc, Obtape, SAFYRE, and I-Stop mesh slings. (*See id.* at 47). Out of the 11,806 patients reviewed, only 86 had reported complications. (*See id.*). The MAUDE database, however, revealed a total of 928 reported complications (700 TVT, 66 SPARC, 1 TVT-O, 149 ObTape, and 12 Monarc slings). (*See id.*). The study ultimately concluded that "[a]lthough rare, major complications of midurethral slings are more common than appear in the literature." (*Id.* at 46). In another study, researchers analyzed Medicare claims from 1999-2001 and concluded that the "complication rates within 1 year after sling surgery among Medicare beneficiaries were found to be higher than those reported in the clinical literature." (Anger et al., *Complications of Sling Surgery Among Female Medicare Beneficiaries*, 109 Obstetrics & Gynecology 707, 707 (2007) [Docket 77-8]).

Ethicon incorrectly asserts that these studies are irrelevant because they did not review the TVT-O specifically. Dr. Blaivas's opinion is that "mesh complications" are under-reported. Such an opinion is clearly supported by these studies. For these reasons, I reject Ethicon's arguments and **FIND** that this opinion is sufficiently reliable.

b. Increasing Frequency of Mesh Complications

In his report, Dr. Blaivas opines that "[i]n the future, there will be an increasing number of patients who have failed initial treatments and an increasing number of 'mesh cripples[.]'" (Blaivas Report [Docket 77-1], at 4). Ethicon argues that this opinion is irrelevant to Ms. Edwards's claims. I agree. Whether future patients may face increasing rates of mesh-related complications will not help the jury decide the issues in this case. Accordingly, this opinion is **EXCLUDED**.

c. Other Physicians' Knowledge

In his report, Dr. Blaivas states that "[i]n the academic circles in which I travel, this and other serious mesh complications were already well known and many of us educators included warnings in our lectures about the use of mesh for the surgical treatment of stress incontinence." (Blaivas Report [Docket 77-1], at 8). Ethicon argues that Dr. Blaivas "is not in a position to provide a reliable assessment concerning what [physicians] knew or did not know." (Mem. in Supp. of Mot. to Exclude Certain Ops. of Jerry G. Blaivas, M.D. [Docket 78], at 8). I disagree. I **FIND** that, as a urologist, Dr. Blaivas is fit to testify what other physicians knew as it relates to the standard of care for designing a mesh product and warning about its potential risks.

d. Ethicon's Alleged Downplaying of Complications

Dr. Blaivas writes that Ethicon downplayed mesh-related complications. For example, Dr.

Blaivas stated in his report that "Ethicon's marketing materials suggest that these complications occur mostly because of faulty surgical technique performed by inexperienced or poorly trained surgeons . . . ." (Blaivas Report [Docket 77-1], at 7). However, according to Dr. Blaivas's first-hand experience and discussion with other physicians, complications can occur "even in experienced hands and when proper surgical technique is used." (*Id.*). In addition, Dr. Blaivas stated that during lectures, "industry representatives would challenge our opinions and data about mesh complication and literally attempt to trivialize them," and that he "witnessed company representatives first hand downplaying these complications in public at post graduate seminars . . . ." (*Id.* at 8-9).

These statements are not expert opinions. Dr. Blaivas is not using his "scientific, technical, or other specialized knowledge" in making these statements. Fed. R. Evid. 702. Therefore, I will not address the admissibility of this testimony here.

e. Complication Rates

Ethicon argues Dr. Blaivas's opinions regarding complication rates should be excluded because they were not included in his report and because his opinions are unreliable. I **FIND** that Dr. Blaivas's opinions on complication rates are unreliable. In discussing complication rates, Dr. Blaivas did not explain his methodology and admitted that it was impossible to calculate an accurate complication rate:

> A: I mean, just to be fair, I mean, I haven't said you should never use it. I mean, look, my contention is that this information should be available not just to the experts but to the implanting doctors worldwide and to the patients.
>
> And I can't tell you if it's 1 percent or 9 percent. I can't tell you that it's going to—I hope it doesn't, maybe after ten years it will be 20 percent, or maybe some of them will get better. I don't know. All I can tell you right now is that it's very clear to me that these kinds of things happen, at the very

least, in the single digit percent rate.

(Blaivas Dep. [Docket 77-2], at 189:11-190-4). In light of this testimony, Dr. Blaivas's opinions regarding complication rates are **EXCLUDED**.

3. Opinions Regarding the Increased Incidence of Complications Related to the Transobturator Approach

Dr. Blaivas opines that the transobturator approach used to implant the TVT-O "increases the risk of nerve injury, leg pain, chronic pain, dyspareunia, and vaginal scarring/banding." (Blaivas Report [Docket 77-1], at 5). Dr. Blaivas does not cite any medical literature to support this statement, but rather cites Ethicon's internal documents. Ethicon contends that these opinions are unreliable because a physician would not utilize internal company documents to form an opinion about medical device complications. *See* Fed. R. Evid. 703 (allowing experts to rely on inadmissible evidence that is of the kind that is *reasonably* relied on by experts in the field).

Rule 703 addresses the circumstances in which an expert may rely on inadmissible evidence to formulate an opinion. "However, the question whether the expert is relying on a *sufficient* basis of information—whether admissible information or not—is governed by the requirements of Rule 702." Fed. R. Evid. 702, advisory committee's note. In other words, whether an expert may rely on particular information is a different question from whether an expert's opinion has a reliable basis. Therefore, I **FIND** that Dr. Blaivas's opinions are not unreliable simply because he relied on internal Ethicon documents.

4. Opinions Relating to Mesh Shrinkage and Degradation

Dr. Blaivas provides several opinions on mesh shrinkage and degradation. He opines that "mesh shrinks unpredictably and asymmetrically, influenced by individual response, bacterial contamination, anatomical location, and time." (Blaivas Report [Docket 77-1], at 9). In addition,

he opines that "polypropylene degrades in vivo," "resulting in stiffening of the mesh, perpetuation of the inflammatory response, creation of a nidus for bacteria and other organisms, and the production of unknown and potentially toxic chemicals." (*Id.*).

Ethicon argues that Dr. Blaivas is unqualified to opine about these topics because he is not a "bio/polymer" chemist and has no background in polymer science. (*See* Mem. in Supp. of Mot. to Exclude Certain Ops. of Jerry G. Blaivas, M.D. [Docket 78], at 11). The plaintiffs contend that Dr. Blaivas has "personally experienced" degradation and shrinkage in his patients. (Pls. Opp. to Def. Ethicon's Mot. and Mem. of Law in Supp. of Its Mot. to Exclude the Ops. and Test. of Jerry Blaivas, M.D. [Docket 104], at 4, 14). But this particular experience is not set out in Dr. Blaivas's expert report. Further, the citation to Dr. Blaivas's deposition provided by the plaintiffs does not relate to degradation. Rather, it relates to Dr. Blaivas's experience with pubovaginal autologous slings. (*See id.* at 14 (citing Blaivas Dep. [Docket 104-1], at 294:21-297:5, 314:1-319:2)). I am unable to locate any reference whatsoever to degradation in Dr. Blaivas's deposition.

The plaintiffs also indicate that Dr. Blaivas cited several scientific studies to support his opinions. But whether an expert's opinions are supported by scientific literature is an issue of reliability, not his qualifications. Here, in light of his lack of experience with mesh degradation or shrinkage, I **FIND** that Dr. Blaivas is unqualified to opine about these topics, and these opinions are **EXCLUDED**.

5. Opinions Related to Product Marketing

Ethicon challenges Dr. Blaivas's statement that "synthetic slings were revived, reinvented and promoted by industry through pervasive advertising and inducements to physicians to perform such surgeries." (Blaivas Report [Docket 77-1], at 2). Dr. Blaivas cites no authority for this

position. Moreover, as Ethicon correctly notes, Dr. Blaivas has no expertise in marketing and therefore is unqualified to make such a broad statement. Accordingly, this opinion is **EXCLUDED**.

6. Hypothetical Clinical Testing

Dr. Blaivas opines that "[a]ppropriate and unbiased clinical testing, if performed, would have shown the problems and complications associated with synthetic slings, including the Gynecare TVT-O." (*Id.* at 8). Dr. Blaivas suggests that Ethicon should have conducted "long-term clinical trials or at least monitor[ed] complications through a registry." (*Id.*). Ethicon argues that Dr. Blaivas's opinions are speculative because he "did not perform any of these hypothetical 'unbiased test[s],' and he does not identify any third-party unbiased testing in support of his conclusions." (Mem. in Supp. of Mot. to Exclude Certain Ops. of Jerry G. Blaivas, M.D. [Docket 78], at 13).

Notwithstanding Ethicon's reliability challenge, I **FIND** that Dr. Blaivas is not qualified to render opinions relating to the product testing. There is no indication in the record that Dr. Blaivas has any experience or knowledge on the appropriate testing a medical device manufacturer should undertake. Therefore, this opinion is **EXCLUDED**.

7. The Competence of Other Physicians in the TVT-O Procedure

Dr. Blaivas states in his report that:

> Claims that make the procedure sound as if it is safer and easier to perform than it actually is are misleading. See above. The goal was sound – a simple, safe, efficacious, outpatient procedure that required minimal surgical skills and could be mastered by surgeons with little training. But the truth is very different. The fact is, it is not so easy to learn these techniques and the ergonomics of the trocars is such that it is easy to misguide them and end up in the wrong place. *Because the*

> *company so trivialized the learning curve and potential complications, many surgeons with inadequate skill and experience perform these surgeries.*

(Blaivas Report [Docket 77-1], at 10 (emphasis added)).

Ethicon argues that this opinion is irrelevant. I agree. Testimony regarding the competence of other physicians will not assist the jury in determining the issues in this case. Accordingly, this opinion is **EXCLUDED**.

8. Alternative Procedures

Dr. Blaivas opines that Ms. Edwards would not have suffered complications if an alternative procedure, such as implantation of a pubovaginal fascial sling, had been used. (*See id.* at 13). Dr. Blaivas writes that pubovaginal slings "using autologous fascia are as effective as synthetic slings" and "are safer than synthetic slings." (*See id.* at 7-8). Ethicon asserts that these conclusions are unreliable because they are not supported by the literature Dr. Blaivas cites. In particular, Ethicon contends that the primary study cited by Dr. Blaivas deals with "intrinsic sphincter deficiency," not stress urinary incontinence. (Mem. in Supp. of Mot. to Exclude Certain Ops. of Jerry G. Blaivas, M.D. [Docket 78], at 15).

It is not clear to me whether this study, *Pubovaginal Fascial Sling for the Treatment of All Types of Stress Urinary Incontinence: Surgical Technique and Long-Term Outcome*, which was authored in part by Dr. Blaivas, applies to stress urinary incontinence or sphincteric incontinence. Despite the study's title, it states that "[t]his article provides an update on the surgical technique and long-term outcome of the full-length autologous rectus fascial sling in the treatment of women with *sphincteric incontinence*." (*See* Blaivas et al., *Pubovaginal Fascial Sling for the Treatment of All Types of Stress Urinary Incontinence: Surgical Technique and Long-Term Outcome*, at 7 (emphasis added)). Yet, the study also appears to state that it advocates for the use of autologous

fascial slings, "[n]o matter what the type" of incontinence. (*Id.* at 14). At the end of the study, in the section titled "References," it cites to several other articles that, by their titles, appear to deal with all types of stress urinary incontinence. (*See id.* at 15 (citing Chaikin et al., *Pubovaginal Fascial Sling for All Types of Stress Urinary Incontinence: Long-Term Analysis*, 160 J. Urology 1312 (1998); Cross et al., *Our Experience with Pubovaginal Slings in Patients with Stress Urinary Incontinence*, 159 J. Urology 1195 (1998)).

Although Ethicon argued in its moving brief that Dr. Blaivas's study applied only to sphincteric incontinence (*see* Defs.' Mem. [Docket 78], at 17), the plaintiffs failed to address this argument in their response (*see* Pls.' Resp. [Docket 104], at 19-20). Accordingly, I **RESERVE** ruling on the reliability of Dr. Blaivas's opinions about pubovaginal slings using autologous fascia until trial. I will conduct a hearing on this issue before Dr. Blaivas is called to testify.

D. Motion to Exclude Ronald Luke, JD, PhD

Ethicon moves to exclude the testimony of Ronald Luke, J.D., Ph.D. in its entirety. Dr. Luke provides two economic opinions in his Report of Economic Damages to Tonya Edwards ("Luke Report"): an opinion regarding Ms. Edwards's past and future loss of earning capacity and an opinion regarding Ms. Edwards's future medical expenses. (*See* Luke Report [Docket 79-1], at 1). Ethicon argues that Dr. Luke's opinions should be excluded because "his opinions are based on speculation, conjecture and assumptions not based in the record." (Mem. in Supp. of Mot. to Exclude Ronald Luke [Docket 80], at 2). Specifically, they argue that "no treating physician or expert has opined that Plaintiff is permanently disabled, which is the operative assumption for Dr. Luke's loss of earning capacity opinion. Further, no treating physician has adopted the pseudo-life care plan prepared by Dr. Luke; nor does Dr. Luke cite to anything in the record supporting the

medical treatment plan" he has identified. (*Id.*). For the reasons discussed below, Ethicon's motion [Docket 79] is **DENIED in part** and **RESERVED in part**.

1. Lost Future Earning Capacity

Dr. Luke's opinion regarding Ms. Edwards's earning capacity was based on several assumptions. For the purposes of the report, Dr. Luke's consulting group assumed as follows:

> We assume that, but for the adverse effects of the mesh implant, Ms. Edwards could have begun work as a cardiovascular technician in January, 2010. The analysis described below assumed that but for the adverse effects of the procedures[,] Ms. Edwards'[s] earning capacity is that of a cardiovascular technician. We further assume that she has no residual earning capacity because her pain and other adverse effects of the procedures prevent her from working.

(Luke Report [Docket 79-1], at 2). Ethicon argues that these assumptions render Dr. Luke's opinion inadmissible because no expert will testify that Ms. Edwards is permanently disabled.

Georgia law allows for recovery of future earnings when a person is disabled, either permanently or temporarily. "Recovery for 'lost earning capacity' is . . . a separate element of damages recovery of which physical injury to the plaintiff resulting in a permanent or total physical disability is the essential element." *Myrick v. Stephanos*, 472 S.E.2d 431, 434 (Ga. App. 1996) (quoting *Leggett v. Benton Bros. Drayage & Storage Co.*, 227 S.E.2d 397, 400 (Ga. App. 1976)). Recovery for "'loss of future earnings' is available where there is proof of loss of definite earnings that would have been received in the future but for an injury, even though the injury is not permanent." *Id.* "Although in general, all future earnings or diminished future earnings are uncertain and difficult of ascertainment, this does not mean that a plaintiff should be denied a recovery. In order to recover, however, there must be evidence from which the jury can estimate, or reasonably infer the loss or decrease in the earning capacity." *Super Disc. Markets, Inc. v. Coney*, 436 S.E.2d 803, 804 (Ga. App. 1993) (citations omitted). Most importantly, "expert

opinion testimony is *not* required to establish the permanency of an injury." *Id.* (emphasis added) (citing *Macon R. & Light Co. v. Streyer*, 51 S.E. 342 (Ga. 1905); *S. Ry. Co. v. Clariday*, 53 S.E. 461 (Ga. 1906)).

Ethicon does not appear to contest that Ms. Edwards is currently unable to work. In Georgia, "[p]ermanent injuries may be proved either by the opinions of physicians, or by proof of facts from which a jury would be authorized to infer that the injuries were permanent." *S. Ry. Co. v. Clariday*, 53 S.E. 461, 462 (Ga. 1906). The plaintiffs intend to present the testimony of Ms. Edwards, Mr. Edwards, and Dr. Steege to support their argument that Ms. Edwards is permanently—or at least temporarily—unable to work. Prior to her injury, Ms. Edwards completed the training to become a cardiovascular technician. In her deposition, Ms. Edwards testified that since her implant surgery, she has suffered from pain and incontinence that render her unable to begin work as a technician. (*See* Tonya Edwards Dep. [Docket 105-1], at 111:15-21). Mr. Edwards also testified that Ms. Edwards still suffers from incontinence and is unable to do everyday housework without experiencing pain and incontinence. (*See* Gary Edwards Dep. [Docket 105-2], at 131:22-132:4, 132:24-133:11). Additionally, Dr. Steege's report states: "While we can likely improve [Ms. Edwards's] quality of life and provide coping skills and behavior modification to manage her pain, a goal of no pain is unrealistic. Though her pain may improve with a series of treatments, very few chronic pain conditions resolve once centralization of pain occurs." (Steege Report [Docket 105-3], at 22). Notably, Ethicon does not challenge Dr. Luke's methodology or qualifications in determining Ms. Edwards's possible lost future earnings. Because Georgia law does not require expert testimony for the jury to estimate or reasonably infer

lost earning capacity or loss of future earnings, I **FIND** that Dr. Luke may testify with regard to these topics.

2. Future Medical Expenses

Dr. Luke's expert report also addresses potential future medical expenses that Ms. Edwards will require. Ethicon contends that Dr. Luke's opinions are irrelevant because they are based on speculation and not supported by the plaintiffs' medical experts.

"Georgia law requires a claimant to prove with reasonable certainty not only that he will sustain future medical expenses, but also the amount of such expenses." *Hendrix v. Raybestos-Manhattan, Inc.*, 776 F.2d 1492, 1507 (11th Cir. 1985) (citations omitted). This means that witnesses must testify to a reasonable degree of certainty as to what future medical necessities the plaintiff may require. *See id.* (finding that "the jury had no evidence upon which to base awards for future medical expenses" because "no witness predicted appellees' future medical expenses with any degree of certainty"); *see also Wayco Enters., Inc. v. Crews*, 272 S.E.2d 745, 747 (Ga. App. 1980) ("Where no evidence is presented from which the jury can ascertain except by mere speculation and conjecture that the plaintiffs would ever have future medical expenses, a charge on this subject is erroneous."). Therefore, without a medical expert testifying as to Ms. Edwards's future medical needs, Dr. Luke's opinions regarding her future medical expenses are irrelevant.

Dr. Luke's report provides "current prices for a list of medical services provided by counsel" which Dr. Luke assumes "are medically necessary and appropriate to meet Ms. Edwards'[s] future medical needs[.]" (Luke Report [Docket 79-1], at 6). The plaintiffs argue that "Dr. Luke's assumptions are fact questions in this specific case about which the jury will make findings based on all the evidence in the case. For each assumption, Plaintiffs have admissible

evidence on which the jury could base a finding that makes the assumption accurate." (Pls.' Mem. in Opp. to Defs.' Mot. to Exclude Ronald Luke, JD, PhD [Docket 105], at 11). However, the plaintiffs do not point to a single assumption by Dr. Luke that is supported by medical testimony. It is the plaintiffs' duty to demonstrate that proper foundation exists for their expert testimony. *See* Fed. R. Evid. 602, 702. However, it is possible that the plaintiffs will present evidence at trial to support Dr. Luke's testimony. If the plaintiffs present evidence indicating *to a reasonable degree of certainty* that Ms. Edwards will require *specific* medical expenses in the future, Dr. Luke's testimony on those expenses may be helpful to the jury. However, the plaintiffs are cautioned that the evidence indicating Ms. Edwards's need for medical expenses must be presented before Dr. Luke's testimony regarding their cost. I therefore **RESERVE RULING** on this part of Ethicon's motion.

E. Motion to Limit the Testimony of Prof. Dr. Med. Bernd Klosterhalfen

Dr. Klosterhalfen offers general causation opinions related to infection, degradation, particle loss, shrinkage, and effective porosity of the TVT-O mesh. This is not the first time I have reviewed *Daubert* challenges to Dr. Klosterhalfen's opinions on these topics. *See In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 617-22 (S.D. W. Va. 2013); *In re Ethicon, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, 2:12-MD-02327, 2014 WL 186872, at *10-11 (S.D. W. Va. Jan. 15, 2014). Wisely wanting to avoid rehashing old arguments, most of Ethicon's motion argues that Dr. Klosterhalfen's opinions are not helpful to the jury in this case because (1) Ms. Edwards did not develop an infection in this case, and (2) the plaintiffs cannot link degradation, particle loss, shrinkage, or effective porosity to Ms. Edwards's injuries. (*See* Mem. in Supp. of Mot. to Limit Testimony of Prof. Dr. Med. Bernd Klosterhalfen [Docket 82], at 3, 5, 11-12). First, as I have

already explained, there is evidence that Ms. Edwards developed an infection in connection with her TVT-O implant. Second, simply because Dr. Klosterhalfen's opinions are limited to general causation does not mean they are not helpful to the jury. If Ethicon believes the plaintiffs cannot establish that the TVT-O caused Ms. Edwards's injuries, it can address this issue at trial.

Ethicon also challenges the reliability of two of Dr. Klosterhalfen's opinions: those based on degradation and those based on effective porosity. Ethicon argues that Dr. Klosterhalfen's testimony about surface degradation should be excluded because Dr. Klosterhalfen "cannot reliably testify that degradation has *any* clinical significance." (*Id.* at 11). The plaintiffs failed to respond to this argument. Without an expert report,[4] I am unable to determine the full scope of Dr. Klosterhalfen's opinions and their foundation. Therefore, I **RESERVE** for trial my ruling on Dr. Klosterhalfen's degradation opinions.

Ethicon also argues that Dr. Klosterhalfen's testimony about effective porosity is unreliable because in his deposition, "Plaintiffs failed to elicit any testimony that Dr. Klosterhalfen was familiar with the details of" the studies on which those opinions are based. (*Id.* at 14). But an expert witness is not required to be familiar with the particular details of each of the studies on which he bases his opinion, as long as an expert in that particular field reasonably relies on the opinions contained in those studies. *See* Fed. R. Evid. 703; *Ferrara & DiMercurio v. St. Paul Mercury Ins. Co.*, 240 F.3d 1, 9 (1st Cir. 2001) ("[W]hen an expert relies on the opinion of another, such reliance goes to the weight, not to the admissibility of the expert's opinion."). Ethicon also

[4] As in *In re C. R. Bard* and *Lewis v. Johnson & Johnson*, the plaintiffs have again failed to provide a full expert report for Dr. Klosterhalfen. Although they have repeatedly argued that Dr. Klosterhalfen is a "percipient fact witness" under no obligation to provide a report, many of his opinions appear to go beyond his status as a fact witness. I previously found that such a failure is harmless under Federal Rule of Civil Procedure 37(c). *See In re Ethicon, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, No. 2:12-cv-4301, 2014 WL 186872, at *10 (S.D. W. Va. Jan. 15, 2014). Despite this prior holding, I will not tolerate continued violations of the plaintiffs' obligation to provide a full expert report under Rule 26. The plaintiffs are advised to provide a more thorough expert report for Dr. Klosterhalfen in future cases.

argues that Dr. Klosterhalfen's opinions are not reliable because they have not been "validated." The plaintiffs fail to respond to this argument, and without an expert report, I again cannot determine the precise bases for these opinions. I therefore also **RESERVE** this ruling for trial.

Accordingly, Ethicon's motion to exclude Dr. Klosterhalfen [Docket 81] is **DENIED in part** with the caveat that I **RESERVE RULING** on the admissibility of Dr. Klosterhalfen's degradation and effective porosity opinions.

F. Motion to Exclude Testimony of Vladimir Iakovlev, M.D.

Ethicon seeks to exclude the testimony of Vladimir Iakovlev, M.D., in its entirety. Dr. Iakovlev is a pathologist. Ethicon argues that "Dr. Iakovlev's proposed testimony goes well beyond his expertise, has no basis for his proposed testimony, much of which is irrelevant, and his opinions are unsupported speculation concerning subjects that are well beyond his expertise." (Mot. to Exclude Test. of Vladimir Iakovlev, M.D. [Docket 85], at 1). Ethicon also argues that Dr. Iakovlev should not be able to testify because his tests on Ms. Edwards's mesh rendered it unable to be tested by any other experts. For the reasons discussed below, Ethicon's motion [Docket 85] is **GRANTED in part**, **DENIED in part**, and **DENIED as moot in part**.

1. Dr. Iakovlev's Method of Testing

First, Ethicon argues that Dr. Iakovlev's opinions should be excluded because the actions he took to test the TVT-O that had been explanted from Ms. Edwards rendered the device untestable by anyone else. One of Ethicon's experts, Shelby F. Thames, Ph.D., stated in her expert report:

> I have been unable to physically and chemically examine the Tonya Edwards explant due to the destructive and compromising methodology used by plaintiff's representatives in handling the sample(s). There was no explant distribution or sample splitting made available to the defendants. The entire sample was

> maintained by plaintiff's counsel and their experts. The explant sample(s) has been physically and chemically altered irreversibly in such a way that prohibits me from observing, testing, and evaluating the explant in its condition and state at explantation. Accordingly, I cannot reach reliable, scientifically valid conclusions via attempting to evaluate the explant in its present state.

(Thames Report [Docket 85-2], at 25).

After Ms. Edwards had the TVT-O removed in January 2012, her explant was placed into formalin for preservation. (Iakovlev Dep. [Docket 85-3], at 194). Plaintiffs' counsel then sent the explant to Dr. Iakovlev for analysis. (*Id.*). Dr. Iakovlev then processed the mesh using what he refers to as "standard procedures." (*Id.* at 195). Dr. Iakovlev took the explant out of the formalin, took gross photographs of the explant, examined it, and made measurements. (*Id.*). After that, Dr. Iakovlev sectioned the mesh and then processed and dehydrated it by exposing it to several solutions of formalin and several concentrations of alcohol. (*Id.* at 197-199). Dr. Iakovlev then covered the explant in melted paraffin, a hydrocarbon wax, and sectioned the paraffin blocks to make slides. (*Id.* at 194-97, 210-13). The paraffin holds the tissue so that it can be cut for slides. (*Id.* at 199). This is the same process that Ethicon's expert pathologist, Wenxin Zheng, M.D., uses to prepare explants for analysis, and is the industry standard. (*See* Zheng Dep. [Docket 112-1], at 49-53; Iakovlev Dep. [Docket 85-3], at 211).

Although Ethicon argues that Dr. Iakovlev's processing of the explant rendered it untestable by any other experts, Dr. Zheng testified that, following Dr. Iakovlev's procedure, he had sufficient material from the explant to make his evaluation. (*See* Zheng Dep. [Docket 112-1], at 130). Dr. Zheng primarily relied upon the slides made by Dr. Iakovlev but also admitted that he had sufficient material to cut more slides. (*Id.* at 131, 263-64). Furthermore, this is not a challenge

to the reliability of Dr. Iakovlev's testing. I therefore **FIND** that Dr. Iakovlev's processing of Ms. Edwards's explant does not require Dr. Iakovlev to be disqualified as an expert witness.

2. Dr. Iakovlev's Expertise

Second, Ethicon argues that Dr. Iakovlev's proposed testimony goes beyond his expertise with regard to the clinical effects of objects removed from the body. However, the plaintiffs have stated that they will not be introducing testimony regarding these issues. (*See* Pls.' Resp. to Defs.' Ethicon Inc. and Johnson & Johnson's Mot. to Exclude Dr. Vladimir Iakovlev [Docket 112], at 5 n.3). Therefore, this portion of Ethicon's motion is **DENIED as moot**.

3. Dr. Iakovlev's Analysis of Pelvic Mesh Explants Generally

Third, Ethicon argues that Dr. Iakovlev lacks reliable methodology for his proposed testimony regarding his general review of pelvic mesh explants. In preparing his expert report, Dr. Iakovlev examined approximately 130 mesh explants, approximately sixty percent of which were transvaginal. (*See* Iakovlev Report [Docket 85-1], at 2). The total number included a mixture of hernia meshes, transvaginal meshes for pelvic organ prolapse, stress urinary incontinence slings from other manufacturers, and six TVT and TVT-O meshes produced by Ethicon. (*See id.*). Ethicon argues that because Dr. Iakovlev's sample was not a large, randomly-selected sample of Ethicon TVT-O meshes used to treat stress urinary incontinence, he cannot (and did not) calculate statistically reliable results. The plaintiffs argue that Dr. Iakovlev's experience examining transvaginal mesh generally aided him in forming his opinion regarding Ms. Edwards's mesh.

To the extent that Ethicon seeks to exclude Dr. Iakovlev's opinions regarding the other explants he examined, I agree that those opinions are inadmissible. Dr. Iakovlev "has given no explanation as to whether [his] is a representative sample size or how he chose the particular

explants analyzed." *Lewis v. Ethicon, Inc.*, No. 2:12-cv-4301, 2014 U.S. Dist. LEXIS 15288, at *2559 (S.D. W. Va. Feb. 3, 2014). "Therefore, I have no information as to the 'potential rate of error' inherent in [his] observations." *Id.* (citing *Daubert*, 509 U.S. at 594). Dr. Iakovlev testified that approximately 80% of the explanted transvaginal mesh slings in his collection were provided by law firms. (*See* Iakovlev Dep. [Docket 85-3], at 155-57). He further testified that he does not know what methodology the plaintiffs' attorneys employed when determining which explants to send him. (*See id.* at 161). Dr. Iakovlev has testified that he requested the plaintiffs' attorneys provide him with all of the mesh explants in their possession; however, he also testified that he has no way of knowing whether they provided him with all of the explanted meshes and does not know how many explanted meshes the attorneys collected in total. (*See* Iakovlev Dep. [Docket 85-3], at 155-57). "A reliable expert opinion must be based on scientific, technical, or other specialized knowledge and not on belief or speculation, and inferences must be derived using scientific or other valid methods." *Oglesby v. Gen. Motors Corp.*, 190 F.3d 244, 250 (4th Cir. 1999) (citations omitted). The plaintiffs have not demonstrated that Dr. Iakovlev's opinions regarding pelvic mesh explants other than Ms. Edwards's were derived using scientific methods. Therefore, Dr. Iakovlev's opinions regarding transvaginal mesh generally are **EXCLUDED**.[5]

To the extent that Ethicon seeks to exclude all of Dr. Iakovlev's testimony because of the sample size he used, their argument is without merit. Dr. Iakovlev may not testify regarding his general conclusions about mesh because his choice of samples lacks scientific methodology. However, that is not a reason to exclude his testimony about Ms. Edwards's mesh, which was

[5] Although Dr. Iakovlev may not testify to his opinions regarding mesh generally, his experience reviewing the mesh in his collection may be relevant to his qualifications. The plaintiffs may ask Dr. Iakovlev questions regarding his review of mesh generally to lay the foundation for his testimony, but are warned not to ask him any opinions he may have come to based on this review.

made after a review of her explant. Therefore, Ethicon's motion is **DENIED** to the extent that it seeks to exclude Dr. Iakovlev's testimony regarding Ms. Edwards's explant due to the unreliability of his samples.

4. Dr. Iakovlev's Analysis of Ms. Edwards's Mesh

Fourth, Ethicon argues that Dr. Iakovlev's opinions regarding Ms. Edwards's explant are speculative and beyond his expertise. They attack different parts of Dr. Iakovlev's opinion, arguing: (1) that he is unqualified to render an opinion regarding his degradation "bark" theory; (2) that he conducted insufficient testing to support his "bark" theory; (3) that his methods of identifying "bark" as degraded polypropylene are unfounded and unreliable; (4) that his degradation opinion is speculation and not reliable expert testimony; (5) that his cause-of-erosion opinion is unreliable; (6) that his cause-of-pain-and-dyspareunia opinion is unreliable; (6) that his ischemia opinion is unreliable; (7) that his edema opinion is unreliable; (8) that his smooth muscle opinion is unreliable; and (8) that his opinion regarding Ms. Edwards's post-explant condition is unreliable. Essentially, all of these arguments can be broken up into two categories: qualifications and reliability. The plaintiffs have agreed that Dr. Iakovlev will not be asked questions regarding "his mesh design analysis and knitting observations, the cause of the erosion suffered by Ms. Edwards, the 'stretch test' performed on a new TVT-O mesh, or urinary symptoms experienced by Ms. Edwards." (Pls.' Resp. to Defs.' Ethicon Inc. and Johnson & Johnson's Mot. to Exclude Dr. Vladimir Iakovlev [Docket 112], at 5-6 n.3). Therefore, those sections of Ethicon's motion are **DENIED as moot**.

A. Dr. Iakovlev's Qualifications to Render an Opinion Regarding Polypropylene Degradation

Ethicon argues that Dr. Iakovlev is unqualified to render an opinion regarding whether there was degraded polypropylene "bark" surrounding Ms. Edwards's mesh. Dr. Iakovlev is a pathologist. Ethicon argues that because Dr. Iakovlev is not a materials scientist and did not submit Ms. Edwards's mesh for chemical testing, he is not qualified to opine that he found degraded polypropylene "bark" when examining Ms. Edwards's explant.

A pathologist is a clinician who provides diagnoses for patient care based on the examination of specimens they receive and relevant clinical information. (*See* Zheng Dep. [Docket 112-1], at 20). Dr. Iakovlev testified that "[e]verything which is taken out of the human body or taken off a human body at the time of death comes for a pathology co-examination, so we have to correlate the devices with the changes in the body, and this is part of our training as pathologists." (Iakovlev Dep. [Docket 112-2], at 30). According to Ethicon's expert, Dr. Zheng, vaginal mesh "just represent[s] a kind of foreign body" for a pathologist to examine. (Zheng Dep. [Docket 112-1], at 46). "[A] pathologist typically deals with many kinds of foreign or medical device[s] removed or explanted from patients . . . . So overall TVT or mesh-related product is part of those medical devices removed and then submit[ted] to the pathology department. The[] pathologist has expertise to examine them[.]" (*Id.*). Dr. Zheng has also testified that pathologists can help diagnose clinical problems, including symptoms such as pain and bleeding. (Zheng Dep. [Docket 112-1], at 22). Dr. Iakovlev teaches a course on clinical pathology. (*See* Iakovlev Dep. [Docket 112-2], at 143).

Ethicon does not question Dr. Iakovlev's pathology credentials; rather, it only argues that as a pathologist, he is unqualified to render an opinion regarding whether the polypropylene in Ms.

Edwards's explant degraded. However, Ethicon's own pathology expert agrees that pathologists are qualified to examine explanted mesh, and Ethicon points to nothing that states the contrary. For this reason and in light of Dr. Iakovlev's experience as a pathologist, I **FIND** that Dr. Iakovlev is qualified to testify regarding degradation.

B. The Reliability of Dr. Iakovlev's Opinions Regarding Ms. Edwards's Mesh

Ethicon also argues that Dr. Iakovlev's various opinions regarding Ms. Edwards's mesh are unreliable. First, they argue that Dr. Iakovlev did not sufficiently test Ms. Edwards's mesh to determine if the "bark" he saw was degraded polypropylene. As discussed above, Dr. Iakovlev is a pathologist, not a materials scientist. He makes his determinations by processing and analyzing explants from the human body. As additionally discussed above, the process Dr. Iakovlev used to analyze the explant is the industry standard in pathology.

Dr. Iakovlev and Dr. Zheng disagree regarding whether the "bark" observed by Dr. Iakovlev is degraded polypropylene. Dr. Zheng also saw the same "bark" rim around the explant that Dr. Iakovlev saw. (*See* Zheng Dep. [Docket 112-1], at 238-244). However, Dr. Zheng hypothesizes that the rim is degenerated collagen, not degraded polypropylene. (*See id.* at 238-40). Mere disagreement among experts is not, in itself, a reason to exclude an expert's testimony. *See Daubert*, 509 U.S. at 580 (stating that the court's "focus must be solely on principles and methodology [the experts use], not on the conclusions that they generate").

The remainder of Ethicon's arguments relate to the reliability of Dr. Iakovlev's opinions regarding cause-of-erosion, smooth muscle, pain, dyspareunia, edema, and ischema. Ethicon's arguments regarding Dr. Iakovlev's cause-of-erosion opinion and smooth muscle opinion are **DENIED as moot** because the plaintiffs have agreed not to question Dr. Iakovlev on these issues.

Ethicon argues that Dr. Iakovlev's opinions regarding the cause of Ms. Edwards's pain and dyspareunia are unreliable because Dr. Iakovlev does not offer a scientific basis for connecting what he sees in the microscope with pain. In his report and at his deposition, Dr. Iakovlev identified areas where he found nerves grown into the pores of Ms. Edwards's explant. (*See* Iakovlev Report [Docket 85-1], at 65-66; Iakovlev Dep. [Docket 112-2], at 243). Dr. Iakovlev opines that "[i]n cases of nerve entrapment, either ingrown or immobilized in the scar or a deformation, movement or external pressure applied to the tissue deforms or moves the mesh and the force can be transferred directly to the nerves." (Iakovlev Report [Docket 85-1], at 4). Dr. Iakovlev also opines that where the nerves connect to the mesh, "an external pressure (intercourse) can compress the nerves against the hardened mesh." (*Id.* at 18). Dr. Iakovlev asserted in his report that "[t]he association of nerve entrapment with pain is well established in medicine and became a common knowledge." (Iakovlev Report [Docket 85-1], at 4). Ethicon does not dispute this contention or point to scientific literature stating the contrary. As the Supreme Court has noted, "[a] reliability assessment does not require, although it does permit, explicit identification of a relevant scientific community and an express determination of a particular degree of acceptance within that community." *Daubert*, 509 U.S. at 594. Therefore, Dr. Iakovlev's statement that it is common knowledge that nerve entrapment can cause pain is not excluded merely because he does not cite to specific medical literature. I therefore **FIND** that Dr. Iakovlev may testify regarding the cause of Ms. Edwards's pain.

Ethicon next argues that Dr. Iakovlev's ischemia and edema opinions are unreliable because they are unsupported. Dr. Iakovlev opines that "ischemia was at least an intermittent contributor to pain experienced by Ms. Edwards." (Iakovlev Dep. [Docket 85-1], at 56). Ischemia

is a "vascular mechanism of pain in [the] human body." (Iakovlev Report [Docket 85-1], at 5). Dr. Iakovlev "detected thrombosed capillaries in [the] Ethicon TVT-O mesh of Mrs. Edwards, which indicates occurrence of circulatory disturbances around the mesh structure." (*Id.*). Dr. Iakovlev bases his opinion on his observation that "[t]here are several thrombosed capillaries and an area of fat degeneration/necrosis" and states that "[n]erve ingrowth shows that the mesh is innervated and the tissue can deliver sensory signal of ischemia." (*Id.*). Ethicon argues that the only evidence of the "several thrombosed capillaries" consists of one single, microscopic slide, and that there is no evidence that capillaries would be perceptible to Ms. Edwards. However, Ethicon does not point to any scientific literature or other authority stating this is insufficient. Notably, Ethicon does not question the methods Dr. Iakovlev used or his qualifications to make these determinations. Rather, Ethicon simply disagrees with Dr. Iakovlev's ultimate opinions. Because Dr. Iakovlev's opinion is based on reliable methodology and evidence, whether there is sufficient evidence to show that Ms. Edwards was suffering from ischemia, edema, and pain can be dealt with by Ethicon on cross-examination. I **FIND** that Dr. Iakovlev may testify regarding ischemia and edema.

Finally, Ethicon argues that Dr. Iakovlev's opinions regarding Ms. Edwards's condition post-explant are unsupported. In his report, Dr. Iakovlev notes that there was a part of Ms. Edwards's mesh that could not be removed from her body. Dr. Iakovlev states that "[t]he remaining part of the mesh can have all of the described above findings to cause her persistent pain. There is a reasonable degree of medical certainty that the remaining mesh parts with the associated involvement of the nerves, muscles and vasculature cause the present symptoms[.]" (Iakovlev Report [Docket 85-1], at 56). However, Dr. Iakovlev is a pathologist, not a treating physician, and he has never examined Ms. Edwards. He has thus never examined the mesh that

remains inside Ms. Edwards. Dr. Iakovlev also does not cite to any specific findings to support his opinion that the mesh remaining in Ms. Edwards is causing her pain. Dr. Iakovlev's opinions regarding the mesh remaining inside of Ms. Edwards after her explant are therefore **EXCLUDED**.

G. Motion to Exclude the Opinions and Testimony of Dr. Russell Dunn, Ph.D., P.E.

Dr. Dunn holds a Ph.D. in chemical engineering and consults on chemical and polymer process and product design issues. (*See* Dunn Report [Docket 91-1], at 1). He will opine that Ethicon's risk assessment process for the TVT-O was inadequate and that the TVT-O is defective. (*See id.* at 4). Dr. Dunn also filed a rebuttal report challenging the opinions of several of Ethicon's experts. Ethicon challenges Dr. Dunn's risk assessment opinion, his opinion at his deposition that polyvinylidene fluoride, or PVDF, is a safer alternative design, and his rebuttal of Ethicon's experts. For the reasons discussed below, Ethicon's motion [Docket 91] is **GRANTED in part** and **DENIED in part**.

1. Risk Assessment Opinions

Dr. Dunn offers opinions regarding Ethicon's risk assessment process—which he calls "Failure Mode & Effects Analysis"—during the design of the TVT-O. He opines that Ethicon's "design documents did not contemplate several [Failure Mode & Effects Analysis] issues and that Ethicon did not have an adequate quality system in place" with respect to Prolene. (Dunn Report [Docket 91-1], at 15). He contends that Ethicon's risk assessment processes failed to account for "polypropylene's inherent tendency to oxidize." (*Id.*). Ethicon argues that this opinion is not helpful to the jury because Dr. Dunn fails to articulate any effect a different quality control process would have had on the TVT-O's design. (*See* Mem. in Supp. of Defs.' Mot. to Exclude the Test. and Ops. of Dr. Russell Dunn, Ph.D., P.E. [Docket 92], at 14-15). Ethicon frames the issue

incorrectly. An expert's testimony must help the jury to "understand the evidence or to determine a fact in issue." Fed. R. Evid. 702. This testimony assists the jury in determining whether Ethicon was negligent in designing the TVT-O. Therefore, Ethicon's motion to exclude Dr. Dunn's risk assessment opinions is **DENIED**.

2. Safer Alternative Designs

Although his expert report does not contain any opinions about safer alternative designs, Dr. Dunn testified in his deposition that mesh using PVDF would be a safer alternative design for the TVT-O. (*See* Dunn Dep. [Docket 91-2], at 123:8-20). Ethicon argues that any opinions related to safer alternative designs should be excluded because Dr. Dunn did not disclose them in his expert report pursuant to Federal Rule of Civil Procedure 26(a)(2)(B), and because they are unreliable. The plaintiffs did not respond to this argument. Accordingly, Dr. Dunn's opinions regarding safer alternative designs are **EXCLUDED**.

3. Rebuttal Report

Dr. Dunn rebuts the opinions of Ethicon's experts, Dr. Kevin Ong, Dr. Shelby Thames, and Timothy Ulatowski. Specifically, he criticizes the conclusions that these experts draw about the Ethicon canine study and Prolene's vulnerability to oxidation. (*See* Dunn Rebuttal Report [Docket 91-13], at 1-2). Ethicon contends that this rebuttal report is unreliable because it is not supported by scientific literature. (*See* Mem. in Supp. of Defs.' Mot to Exclude the Test. and Ops. Of Dr. Russell Dunn, Ph.D., P.E. [Docket 92], at 17-19).

Despite Ethicon's objection, I **FIND** that Dr. Dunn's rebuttal report has sufficient indicia of reliability. His rebuttal report simply criticizes the methods Ethicon's experts used to come to their conclusions. Dr. Dunn writes that the Ethicon canine study failed "to recount its materials and

methods of reproducibility" and used "a control group that does not comport with the implanted Prolene samples." (Dunn Rebuttal Report [Docket 91-13], at 1). He contends that Ethicon's experts ignored polypropylene's propensity to degrade, despite the use of antioxidants. (*See id.* at 1). He cites several scientific studies for his opinions and states that the sources relied on by Ethicon's experts "favor specific data while ignoring others[.]" (*Id.*). Therefore, Ethicon's motion on this issue is **DENIED**.

H. Motion to Exclude the Opinions and Testimony of Dr. Abhay Pandit, Ph.D.

Dr. Pandit is a biomedical engineer. He plans to testify that the TVT-O was defectively designed and that Ethicon failed to adequately test the TVT-O. Ethicon moves to preclude Dr. Pandit's testimony in its entirety. For the reasons set forth below, Ethicon's motion [Docket 95] is **GRANTED in part** and **DENIED as moot in part**.

1. Leaching Chemicals

Dr. Pandit opines that the TVT-O is defective because, among other things, when polypropylene degrades in vivo, "chemicals are produced that leach into the surrounding tissues." (Pandit Report [Docket 95-1], at 6). He states that Ethicon failed to perform appropriate tests for "these chemicals and their effects." (*Id.*). Ethicon argues that these opinion are unreliable. Dr. Pandit cites no scientific support for these opinions, and he was unable to name which particular chemicals are produced:

> Q. Do you have an opinion, to a reasonable degree of scientific certainty, that when oxidation occurs breaking the chemical bonds, that chemicals are produced that leach into the surrounding tissues?
>
> A. Yeah.
>
> Q. What chemicals?

A. I'm not so sure which ones they are.

(Pandit Dep. [Docket 95-3], at 162:15-22). It is clear from this exchange that Dr. Pandit's opinions on chemical leaching and Ethicon's failure to test for such leaching are not reliable. Therefore, these opinions are **EXCLUDED**.

2. Failure to Test

Dr. Pandit claims that Ethicon failed to adequately test the TVT-O. For instance, he states that pre-clinical testing was inadequate; Prolene mesh was not tested for shrinkage, degradation, or stiffening; the "inside-out approach" for surgical implantation was not tested appropriately; and the trocar design was not tested appropriately. (Pandit Report [Docket 95-1], at 1-2). Ethicon contends that Dr. Pandit is not qualified to offer these opinions because he failed to identify any specific experience, training, or education in designing or testing implantable devices. In his expert report, Dr. Pandit simply states, without elaboration, that he "has extensive experience in the design and testing of implantable medical devices, including surgical mesh." (Pandit Report [Docket 95-1], at 1). The plaintiffs failed to attach Dr. Pandit's curriculum vitae to his expert report, so I am unable to verify this statement. When asked about this statement at his deposition, Dr. Pandit's response was vague:

> Q. What experience do you have in the design and testing of surgical mesh used for the treatment of stress urinary incontinence specifically?
>
> A. So my experience in testing of implantables is a very fundamental approach of looking at host responses in the body. So I'm an expert in host responses. I design material for host response to understand what the host response is. And the approach I take is, you know, is looking at the principles involved in how one does the studies for the intended applications. So in the context of surgical meshes, I would have had implanted surgical meshes in quite a few projects before, and looking at what the host response is.

(*See* Pandit Dep. [Docket 95-2], at 24:14-25:5). He also stated that he has "used polypropylene several times" in the last 22 years in "multiple situations in the body." (*Id.* at 25:16-17, 24-25).

In light of Dr. Pandit's vague explanations and plaintiffs' counsels' failure to attach Dr. Pandit's curriculum vitae, I am unable to determine what precise qualifications he has to opine about designing or testing implantable medical devices. Therefore, the plaintiffs failed to carry their burden to demonstrate that Dr. Pandit should be permitted to testify on this issue and Dr. Pandit's opinions regarding testing are **EXCLUDED**. *See Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998) ("As in all questions of admissibility, the proffering party must come forward with evidence from which the court can determine that the proffered testimony is properly admissible.").

3. Safer Alternative Designs

Although he did not discuss safer alternative designs in his expert report, Dr. Pandit testified in his deposition that Ethicon should have used materials other than Prolene in the TVT-O. Ethicon contends that these opinions should be excluded because they were not contained in his expert report and because they are unreliable.

Whether or not these opinions should be excluded for failing to appear in Dr. Pandit's expert report, they are unreliable. Dr. Pandit refused to say which particular materials would be suitable as an alternative design:

> Q. Can you tell me today what modified synthetic materials that you have described that may have these additives or changes that may be appropriate for the use in the treatment of stress urinary incontinence?
>
> A. Yes. One other ideas could be, I don't want to give Ethicon ideas on what they should be doing.
>
> Q. Sorry, you're going to have to.

> A. I mean I'm giving our IP to them, telling them what they should be doing in terms of constructs.

(Pandit Dep. [Docket 95-2], at 38:8-19). The plaintiffs state that "Dr. Pandit identified PVDF and relied upon Ethicon documents which compare the mechanical properties and *in vivo* reactivity of polypropylene and PVDF." (Pls.' Resp. to Defs.' Mot. to Exclude the Testimony and Opinions of Dr. Abhay Pandit, Ph.D. [Docket 109], at 18). But the plaintiffs do not cite to any portion of Dr. Pandit's expert report or deposition for this statement. Without an explanation from Dr. Pandit about which particular materials would be suitable alternative designs, these opinions are unreliable and are **EXCLUDED**.

4. Laser Cutting Mesh

In his deposition, Dr. Pandit stated that the TVT-O was defective because it uses laser-cut mesh. (*See* Pandit Dep. [Docket 95-2], at 69:16-22; 99:3-101:17). He also claimed that Ethicon failed to test the effects of laser cutting. (*See id.* at 99:10-12). He opines that "laser treatment does damage [to] polymer structures" and that antioxidants are lost as a result of laser cutting. (*Id.* at 99:20-21; 100:4-10). However, Dr. Pandit admitted that he could "absolutely not" testify to a reasonable degree of medical certainty that laser-cut mesh is safer than mechanically cut mesh. (*Id.* at 100:21). Therefore, this opinion is unreliable and is **EXCLUDED**.

5. Cancer

The plaintiffs state that Dr. Pandit will not opine about the TVT-O potential to cause cancer. (*See* Pls.' Resp. to Defs.' Mot. to Exclude the Testimony and Opinions of Dr. Abhay Pandit, Ph.D. [Docket 109], at 17). Ethicon's motion on this issue is accordingly **DENIED as moot**.

I. Motion to Exclude the Opinions and Testimony of Dr. Scott Guelcher, Ph.D.

Dr. Guelcher holds a Ph.D. in chemical engineering and a post-doctoral degree in biomedical engineering. He is currently a professor of chemical and biomolecular engineering. He offers the following opinions in this case: (1) the human body "does not stop responding" to mesh until it is removed entirely, (2) the "dynamic environment where these meshes are implanted coupled with the chronic response of the body leads to polymer instability, embrittlement, structural degradation and other changes," (3) it is not possible to guarantee that the TVT-O will perform its intended function after implantation, and (4) the TVT-O mesh is not inert and can change after implantation, which may lead to adverse events for the patient. (Guelcher Report [Docket 97-1], at 3).

Ethicon first argues that Dr. Guelcher's general causation testimony is not helpful to the jury because the plaintiffs cannot prove specific causation and because no expert can say that degradation is clinically significant. As I have already explained, general causation opinions are helpful to the jury and fit the facts of this case regardless of whether the plaintiffs may ultimately fail to carry their burden to show that Ms. Edwards was harmed by her TVT-O implant.

Second, Ethicon argues that Dr. Guelcher's opinions are unreliable and unhelpful because they relate only to generic polypropylene, not Prolene mesh. This argument, too, has already been rejected. Therefore, Ethicon's motion to exclude Dr. Guelcher is **DENIED**.

IV. Conclusion

I emphasize that my rulings *excluding* expert opinions under Rule 702 and ***Daubert*** are dispositive of their admissibility in this case, but that my rulings *not to exclude* expert opinions are not dispositive of their admissibility. In other words, to the extent that certain expert opinions

might be cumulative or might confuse or mislead the jury, they may still be excluded under Rule 403 or some other evidentiary rule.

I am particularly concerned about cumulative testimony. For instance, the plaintiffs offer at least five experts to opine on degradation, three experts on the insufficiency of Ethicon's warnings, and three experts on safer alternative designs. The defendants offer three experts on degradation. The parties will not be permitted to call all of these experts at trial, and they should plan accordingly.

For the reasons set forth above, Ethicon's Motion to Exclude the Opinion Testimony of John F. Steege, M.D. [Docket 73] and Ethicon's Motion to Exclude the Opinions and Testimony of Dr. Scott Guelcher, Ph.D. [Docket 97] are **DENIED**. Ethicon's Motion to Limit the Testimony of Bruce Rosenzweig, M.D. [Docket 75] and Motion to Exclude Testimony of Vladimir Iakovlev, M.D. [Docket 85] are **DENIED in part**, **DENIED as moot in part**, and **GRANTED in part**. Ethicon's Motion to Exclude Certain Opinions of Jerry G. Blaivas, M.D. [Docket 77] is **DENIED in part**, **GRANTED in part**, and **RESERVED in part**. Ethicon's Motion to Exclude Ronald Luke, JD, PhD [Docket 79] and Motion to Limit the Testimony of Prof. Dr. Bernd Klosterhalfen are **DENIED in part** and **RESERVED in part**. Ethicon's Motion to Exclude the Opinions and Testimony of Dr. Russell Dunn, Ph.D., P.E. [Docket 91] is **GRANTED in part** and **DENIED in part**. And Ethicon's Motion to Exclude the Opinions and Testimony of Dr. Abhay Pandit, Ph.D. [Docket 95] is **GRANTED in part** and **DENIED as moot in part**.

The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: July 8, 2014

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE